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EXAMINER	
SUNG, CHRISTINE	
ART UNIT	PAPER NUMBER
2884	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/684,965	LEWIS ET AL.	
	Examiner	Art Unit	
	Christine Sung	2884	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10,12-24 and 26-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-10,12-24 and 26-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1. The amendment filed on September 29, 2006 has been accepted and entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2-6, 8, 10, 13-14, 16, 20-21, 26-31, 33, 35-36, 38-40, 44 and 50-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Horigane (WO/01/18527, see US Patent 6,537,826 B1 for translation as well as for citations).

Regarding claim 2, Horigane discloses a spectral acquisition system, comprising:

an exploration subsystem (figure 2) operative to expose interior portions of a three-dimensional sample (see figure 3a, element 22, a rotary blade cuts open element 11, the 3-D sample), wherein the exploration subsystem includes a cutting implement (figure 2, element 22) and a guide (element 23), and

a spectral acquisition subsystem operative to acquire images of the interior portions exposed by the exploration subsystem (see column 5, lines 37-46).

Regarding claim 3, Horigane discloses that the exploration subsystem includes an actuator operative to advance the cutting implement (see figure 2, the fixing jig element 23, advances through the cutting implement, element 22).

Regarding claim 4, Horigane discloses that exploration subsystem is operative in the field of view of the spectral acquisition system (this is an inherent property of the system because if

the sample is not within the field of view of the detection system, it is impossible to spectrally analyze the sample).

Regarding claim 5, Horigane discloses a mechanical link, an electrical link, and a digital link (elements required for movement of the exploration system, in figure 2) between the exploration subsystem and the spectral acquisition system.

Regarding claim 6, Horigane discloses including a control module operative to control the exploration subsystem and process information from the spectral acquisition system (see claim 6).

Regarding claim 8, Horigane discloses that the spectral acquisition subsystem operates in near-infrared or mid-infrared spectral regions (Column 3, line 10-13, IR spectroscopy).

Regarding claim 10, Horigane discloses that the exploration subsystem includes a sample embedding substance (Figure 3(a), element 13, a filler material for embedding the sample, element 11).

Regarding claim 16, Horigane discloses a spectral acquisition method comprising:

Actively processing a sample top expose characteristics of interior portions of the sample (the sample, element 11, is cut open by a rotary blade to expose it for analysis),

Acquiring spectral information from the interior portions of the sample exposed in the step of exposing (column 5, lines 37-46), wherein the steps of actively processing and acquiring are applied to a friable material (the sample is a fragile sample, i.e. a chemical product or a seed) and

preparing the friable material to withstand the step of actively processing before the step of actively processing, wherein the step of preparing includes fixing the sample in a fixing

material (See figure 3(a), sample element 11 is fixed by a filler material, element 13) and the step of actively processing includes cutting the sample (see figure 3(a), element 22, a rotary blade cuts the sample, element 11 prior to analysis).

Regarding claims 13-14, Horigane discloses that the steps of preparing, actively processing, and acquiring are applied to a bulk pharmaceutical material/dosage unit (Horigane discloses that the material is a chemical product, see column 1, lines 13-20).

Regarding claim 20, Horigane discloses that the steps of actively processing expose planar interior surfaces (see figure 3(b), element 15, exposed interior planar surface of the sample).

Regarding claim 21, Horigane discloses that the step of actively processing and the step of acquiring both take place with the sample in a position constrained in at least one dimension (the sample, element 11 is constrained in all dimensions by the sample holder depicted in figure 1, during the processing and acquiring steps).

Regarding claim 53, Horigane discloses the step of acquiring operates in near-infrared or mid-infrared spectral regions (Column 3, line 10-13, IR spectroscopy).

Regarding claim 28, Horigane discloses a spectral acquisition system, comprising:

means for holding (element 10) a friable pharmaceutical tablet (element 11, column 1, lines 13-20), means for exposing interior portions of the friable pharmaceutical tablet, wherein the means for exposing includes a cutting implement (figure 2, element 22) and a guide (Figure 2, element 22),

and means for obtaining spectral images of the exposed interior portions (see column 5, lines 37-46).

Regarding claim 26, Horigane discloses that the means for holding include means for embedding the pharmaceutical tablet (Figure 3(a), element 13, a filler material embeds the sample).

Regarding claim 27, Horigane discloses that the means for holding include a holding wax or paraffin (column 1, lines 54-59).

Regarding claim 29, Horigane discloses that the means for exposing includes means for advancing the cutting implement (the rotary blade, element 22 traverses the sample holder, element 10, see column 7, lines 39-41).

Regarding claim 30, Horigane discloses that the means for holding is operative to hold the sample in the field of view of the means for obtaining spectral images during operation of the means for exposing (this is an inherent property of the system because if the sample is not within the field of view of the detection system, it is impossible to spectrally analyze the sample).

Regarding claim 31, Horigane discloses a mechanical link, an electrical link, and a digital link (elements required for movement of the exploration system, in figure 2) between the exposing means and the means for obtaining spectral images.

Regarding claim 33, Horigane discloses that the means for obtaining spectral images operate in near-infrared or mid-infrared spectral regions (Column 3, line 10-13, IR spectroscopy).

Regarding claim 35, Horigane discloses a spectral acquisition method comprising, positioning a pharmaceutical tablet (Horigane discloses positioning a chemical product, column 1, lines 14-20, in a sample holder, figure 3a, element 11) within an optical field of view of an acquisition system (this is an inherent property of the system because if the sample is not within

the field of view of the detection system, it is impossible to spectrally analyze the sample), removing material from the tablet within the field of view (element 22 is a rotary blade that cuts away a section of the sample, see figure 3(b), the section is then out of the field of view), and acquiring an image of the tablet by the acquisition system after the step of removing (column 3, lines 6-18).

Regarding claim 36, Horigane discloses the steps of removing and acquiring are applied to a friable tablet (Horigane disclose the problem that the sample is fragile and can crumble easily, (column 1, lines 43-53), and further including the step of preparing the friable tablet to withstand the step of removing (Horigane discloses the step of freezing the sample such that it is more durable during the removal or cutting step, see column 2, lines 19-20).

Regarding claims 38-40, Horigane discloses the step of preparing includes fixing the sample in a fixing material (see figure 3(a), element 11, the sample is fixed in a filler material, element 11a) and the step of removing includes cutting the sample with a blade (Sample element 11, is cut by rotary blade element 22).

Regarding claim 44, Horigane discloses that the step of removing and the step of acquiring both take place with the sample in a position constrained in at least one dimension (the sample, element 11 is constrained in all dimensions by the sample holder depicted in figure 1, during the processing and acquiring steps).

Regarding claim 50, Horigane discloses that the step of acquiring an image acquires an image in near-infrared or mid-infrared spectral regions (Column 3, line 10-13, IR spectroscopy).

Regarding claims 51- 52, Horigane discloses the step of acquiring is operative to obtain an image from material removed by the step of removing (spectral images are made after the cut (see figure 3(b), element 15) is made in the sample).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 17, 22, 41 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horigane (WO/01/18527, see US Patent 6,537,826 B1 for translation as well as for citations).

Regarding claims 22 and 45, Horigane discloses all of the limitations set forth in claim 16 and 35 respectively, but does not explicitly state that the step of actively processing and the step of acquiring both take place as part of an automated sequence. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have automated the processing and acquiring steps, since it has been held that broadly providing a mechanical or

automatic means to replace manual activity which ahs accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192. Further, one of ordinary skill in the art would be motivated to automate the process in order to increase manufacturing efficiency, as automation is a well-known technique for increasing efficiency.

Regarding claims 17 and 41, Horigane discloses the limitation set forth in claims 16 and 35, respectively, but does not specify repeating the steps of actively processing and acquiring to create a data set of information about different interior portions of the sample. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to repeat acquisition of data and sampling from different parts of the sample, as such repetition will increase the accuracy of the detected data.

7. Claims 7, 9, 15, 18-19, 32, 34, 37 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horigane (WO/01/18527, see US Patent 6,537,826 B1 for translation as well as for citations) in view of Folestad (US Pre Grant Publication 2002/0125434 A1).

Regarding claim 7, Horigane discloses the limitation set forth in claim 1, and further discloses that the spectral acquisition system includes a detection system (see above paragraphs), but does not disclose the specifics of the spectral acquisition system, namely that it includes a two-dimensional array detector and a spectrally selective device. However, Folestad discloses a conventional spectral system that includes a two-dimensional array detector (figure 7, element 18) and a spectrally selective device. One of ordinary skill in the art would be motivated to use the well-known and conventional two dimensional array detector and selection device as disclosed by Folestad with the invention as disclosed by Horigane in order to increase the imaging area, thus decreasing the acquisition time.

Regarding claims 9 and 34, Horigane does not explicitly state that a vent or airborne waste collection system is connected to the apparatus or system as disclosed in claims 9 and 34. However, Folestad discloses that his invention is directed to on-line tablet detection (paragraph [0009]). One of ordinary skill in the art would be motivated to include a vent with the invention as disclosed by Horigane in order to reduce detector contamination.

Regarding claims 15 and 37, Horigane discloses that the sample could be any chemical product, but does not specify a pharmaceutical pill. However, spectral analyses of such element is disclosed by Folestad (see element 14, pill). Further, pills by definition contain at least one active ingredient and one inert ingredient (the binder in which the active ingredient is dispersed). One of ordinary skill in the art would be motivated to specifically analyze the pill as disclosed by Folestad with the invention as disclosed by Horigane, as such elements are commonly analyzed.

Regarding claims 18-19, Horigane does not explicitly disclose a step of selecting a spatial separation between the steps of actively processing to be on the same order as that of a spatial resolution of the step of acquiring. However, when taking multiple images, as disclosed by Folestad; (paragraph [0025]), it would be obvious to one having ordinary skill in the art at the time the invention was made to have such images of the same resolution so that when the images are processed it does not create discrepancies or additional error in the image processing.

Regarding claim 32, Folestad discloses a means for controlling the means for exposing and for processing information from the means for obtaining spectral images (paragraph [0040]).

Regarding claims 47-49, Horigane discloses that the apparatus is used for material processing areas of art and to determine the quality of the sample (see column 2, line 8-10). Horigane does not specify the exact industrial processing type, however, it would have been

obvious to one having ordinary skill in the art at the time the invention was made to apply the method as disclosed by Horigane in a conventional pill making/checking method as disclosed by Folestad in order to accurately monitor manufactured pills.

8. Claims 12, 23-24, 42-43 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horigane (WO/01/18527, see US Patent 6,537,826 B1 for translation as well as for citations) in view of Nelson (US Pre Grant Publication 2006/0019409 A1).

Regarding claim 23, Horigane discloses a spectral acquisition method, comprising:

Actively processing a sample top expose characteristics of interior portions of the sample (the sample, element 11, is cut open by a rotary blade to expose it for analysis),

Acquiring spectral information from the interior portions of the sample expose in the step of exposing (column 5, lines 37-46). Horigane discloses general acquisition of spectral information but does not specify the step of processing the spectral information acquired in the step of acting to obtain 2-D chemical image planes and reconstructing at least one 3-D image from the 2-D chemical image planes. However, such type of processing of spectral images is a well-known step in conventional volumetric spectrometers (see Nelson, paragraphs [0010] and 0091]). It would be obvious to one having ordinary skill in the art at the time the invention was made to process the spectral information disclosed by Horigane by the method as disclosed by Nelson in order to have greater accuracy in determining three dimensional sample composition.

Regarding claim 12, Horigane discloses the steps of actively processing and acquiring are applied to a friable material and further including the step of preparing the friable material to withstand the step of actively processing before the step of actively processing (the sample,

element 11, is a friable material (a seed or other chemical material) that is prepared to withstand processing by freezing the friable material).

Regarding claim 24, Horigane discloses that the step of acquiring operates in NIR or MIR spectral regions (Column 3, line 10-13, IR spectroscopy).

Regarding claims 42-43, Horigane discloses the limitations set forth in claim 41, but does not disclose the specific processing steps disclosed in the claims. However, Nelson discloses taking multiple images of the same spatial resolution (inherent that they are of the same spatial resolution because using the same detector) (paragraph [0091]) and further discloses interpolating the data received (See paragraph [0093]). It would have been obvious to one of ordinary skill in the art, at the time the invention was made to have used the particular processing technique disclosed by Nelson with the invention as disclosed by Horigane in order to increase the resolution of the images detected.

Regarding claim 46, Horigane discloses the limitation set forth in claim 35, but does not explicitly state the processing specifics. Horigane discloses general acquisition of spectral information but does not specify the step of processing the spectral information acquired in the step of acting to obtain 2-D chemical image planes and reconstructing at least one 3-D image from the 2-D chemical image planes. However, such type of processing of spectral images is a well-known step in conventional volumetric spectrometers (see Nelson, paragraphs [0010] and 0091]). It would be obvious to one having ordinary skill in the art at the time the invention was made to process the spectral information disclosed by Horigane by the method as disclosed by Nelson in order to have greater accuracy in determining three dimensional sample composition.

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

10. The indicated allowability of claims 2-3, 16, 23, 28-29 and 35-52 is withdrawn in view of the newly discovered reference(s) above. Rejections based on the newly cited reference(s) are above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Sung whose telephone number is 571-272-2448. The examiner can normally be reached on Monday- Friday 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christine Sung

Examiner
Art Unit 2884

CS